UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN B. SULLIVAN, and FINDLAY E. RUSSELL

Appeal No. 2006-0220
Application No. 08/405,454

HEARD: FEBRUARY 07, 2006

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 40-42 and 50. Claims 54 and 55, the only remaining pending claims, were withdrawn from consideration as drawn to a non-elected invention.

Claim 40 is illustrative of the subject matter on appeal and is reproduced below:

> 40. An antivenom pharmaceutical composition for treating a snakebite victim, comprising Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier, wherein said antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the Crotalus genus.

The references relied upon by the examiner are:

Stedman's Medical Dictionary (Stedman's) p. 94 (23rd ed., Williams and Wilkins Co., 1976)

Smith et al. (Smith), "Immunogenicity and kinetics of distribution and elimination of sheep digoxin-specific IgG and Fab fragments in the rabbit and baboon," Clin. Exp. Immunol., Vol. 36, pp. 384-96 (1979)

Sullivan et al. (Sullivan), "Isolation and Purification of Antibodies to Rattlesnake Venom by Affinity Chromatography," Proc. West. Pharmacol. Soc., Vol. 25, pp. 185-92 (1982)

Coulter et al. (Coulter), "Simplified Preparation of Rabbit Fab Fragments," J. Immunol. Methods, Vol. 59, pp. 199-203 (1983)

GROUNDS OF REJECTION

I. Claims 40-42 and 50 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter.

II. Claims 40-42 and 50 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter, Smith and Stedman's.

We affirm rejection I. Having disposed of all claims on appeal we do not reach the merits of rejection II.

CLAIM GROUPING

According to appellants (Brief, page 4), the claims stand or fall together. Accordingly, we limit our discussion to representative independent claim 40. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991). Claims 41, 42 and 50 will fall together with claim 40.

PROCEDURAL BACKGROUND

This is the second time this application is before us on appeal. In the first appeal, Appeal No. 2001-1255 ('1255), this Merits Panel found all claims to be obvious in view of the combination of Sullivan and Coulter.[1] See Decision, mailed January 29, 2003. For clarity, we reproduce claims 40 and 45 as they appeared in the '1255 appeal:

> 40. An antivenom composition comprising Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier.
>
> 45. Fab fragments which bind specifically to a venom of a snake of the Crotalus genus, and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using an anti-Fc antibody.

As can be seen from a comparison of claims 40 and 45, the Fab fragments of claim 45 are the same as those found in the composition of claim 40. Stated differently, claim 40 could have been written as "[a]n antivenom composition comprising the Fab fragments of claim 45 and a pharmaceutically acceptable carrier."

According to appellants (Brief, page 4), "[t]he issues in this appeal arise directly from the Board's decision in the [p]revious ['1255 a]ppeal." However, upon consideration of appellants' arguments as they appear on page 4 of their Brief, it appears that appellants have misread, or misinterpreted, the Board's

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[1] Specifically, we affirmed the examiner's rejection of claims 45-47 under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter. In addition, we introduced a new ground of rejection of claims 40-42 under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter.

Decision in the '1255 appeal. Accordingly, we take this opportunity to review appellants' discussion of the '1255 appeal.

> According to appellants (Brief, page 4), alteration original,
>
> > The new ground of rejection [entered into the record in the '1255 appeal] was based upon the Board's belief that the mere recitation of an "antivenom composition" in the preamble did not result in the claims requiring a pharmaceutical activity. "There is no requirement in this claim that the Fab fragments exhibit a pharmaceutical activity." [Paper No. 45 at p. 9.]

Notwithstanding what appellants assert to be the "Board's belief," in addressing the "New Ground of Rejection" at page 9 of the '1255 appeal, the Merits Panel stated, "[a]s explained above, the mere statement of a new use, in this case 'an antivenom' for an otherwise old or obvious composition cannot render a claim to the composition patentable. Zierden[2], and Pearson[3]." Stated differently, having found the composition to be obvious in view of the prior art, the term "antivenom" as it appears in the preamble cannot render the claim to the composition patentable. Furthermore, despite appellants' assertion, the term "pharmaceutical activity" does not appear in the statement of the "New Ground of Rejection" on pages 9-10 of the Decision.

To the contrary, the Merits Panel mentions the term "pharmaceutical activity" in the context of then pending claim 45, drawn to a Fab fragment.[4] For clarity, we note that the following statement was made in response to appellants' arguments addressing the pharmaceutical activity of the claimed Fab fragment –

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[2] In re Zierden 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969).

[3] In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

[4] Note, no claim before us on this appeal is drawn to a Fab fragment.

"[t]here is no requirement in this claim that the Fab fragments exhibit a pharmaceutical activity, therefore, we are not persuaded by appellants' attempt to distinguish their claimed Fab fragments on this basis." Decision, page 9.

Nevertheless, by taking the Decision out of context, appellants speculate that the Merit Panel "believed that the combination of Sullivan et al. and Coulter et al. would have suggested using Fab antivenom fragments to detect Crotalus venom, not to treat envenomation with Crotalus venom." Since the previous Merit Panel never reached the issue of "treatment," or for that matter "pharmaceutical activity," it's unclear how appellants' can divine, from the prior Decision, what the Merit Panel believed with regard to either of these issues as they apply to the prior art of record in the '1255 appeal.

Given the foregoing, we begin by highlighting the findings and holding of the relevant rejections of the '1255 appeal:

Then pending claims 45-47:

In the '1255 appeal, the examiner found that Sullivan taught purified antivenin polyvalent antibodies against venom from a snake of the Crotalus genus. Decision, page 8. Sullivan, however, did not teach Fab fragments. To make up for the deficiency in Sullivan, the examiner relied on Coulter to teach a method for producing F(ab) fragments that are free of Fc and extraneous protein, for use in enzyme immunoassays (EIAs) due to the higher sensitivity obtained when Fab fragments are used instead of intact IgGs. Decision, page 8.

In responding to the examiner's rejection, appellants' arguments were directed to the use of the Fab fragments as an antitoxin. See Decision, page 8,

"[i]n our opinion, appellants ... place to great a weight on one potential use, as an antitoxin, of the claimed 'Fab fragments[.]'" In contrast, we found that the claimed Fab fragments were prima facie obvious over the combination of Sullivan and Coulter. Regarding appellants' focus on the intended use of their Fab fragments we reminded appellants (Decision, page 7), "'the mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable.' In re Zierden 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969)." Accordingly, the rejection of claim 45 under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter was affirmed. Then pending claims 46 and 47 fell together with claim 45. Decision, page 9.

For their part, appellants did not request reconsideration, nor did they appeal our decision to affirm the rejection of claims 45-47. Instead, appellants conceded and subsequently cancelled claims 45-47.

Then pending claims 40-42:

As set forth on page 9 of the Decision, claim 40 as it appeared in the '1255 appeal was "drawn to an antivenom composition comprising the Fab fragments of appellants' claim 45 and a pharmaceutically acceptable carrier." As set forth on pages 9-10 the Decision in the '1255 Appeal, the combination of Sullivan and Coulter teach a composition comprising Fab fragments and a pharmaceutical carrier (PBS) as required by then pending claim 40. Accordingly, the Merits Panel entered a new ground of rejection under 35 U.S.C. § 103

finding claims 40-42[5] unpatentable over the combination of Sullivan and Coulter. Id.

For their part, appellants did not request reconsideration, nor did they appeal our decision to affirm the rejection of claims 45-47. Instead, according to appellants (Brief, page 5), they

> amended the preamble of claim 40 to expressly recite that the antivenom composition is an "antivenom pharmaceutical composition for treating a snakebite victim." Moreover, [a]ppellants also amended the body of claim 40 to recite that the antivenom pharmaceutical composition "neutralizes the lethality of the venom of a snake of the Crotalus genus."

For clarity we reproduce now pending claim 40 with underlining to identify the portion of the claim that is new relative to the manner in which it appeared in the '1255 appeal.

> 40. An antivenom pharmaceutical composition for treating a snakebite victim, comprising Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier, wherein said antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the Crotalus genus.

On this record, the examiner rejected claim 40 under 35 U.S.C. § 103 as being unpatentable over the combination of Sullivan and Coulter, or alternatively over the combination of Sullivan, Coulter, Smith and Stedman's.

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[5] As discussed in n. 2 of the '1255 Decision, appellants did not dispute the examiner finding that Sullivan taught IgG(T) antibodies, that appellants did not dispute this point. Accordingly, no further discussion was provided for claims 41 and 42, which correspond to claims 46 and 47, and further limited claim 40 to IgG(T) Fab fragments. See e.g., Decision, page 10.

To be clear, there are only two differences between the composition of claim 40 now before us on appeal and the composition previously before us in claim 40 of the '1255 appeal. The first difference is a recitation of intended use that states that the pharmaceutical composition is for treating a snakebite victim.

The second difference is the insertion of a functional limitation that requires the pharmaceutical composition to have the property of neutralizing the lethality of the venom of a snake of the Crotalus genus. As discussed above, and in the Decision of the '1255 appeal, Sullivan and Coulter teach the remaining portion of claim 40 - a "composition comprising Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier."

Against this background we consider the merits of the pending rejections.

DISCUSSION

Sullivan in view of Coulter:

I. A pharmaceutical composition for treating a snakebite victim:

As explained on page 7 of the Decision in the '1255 appeal, the mere statement of a new use[6] for an otherwise old or obvious composition cannot render a claim to the composition patentable. In re Zierden 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) ("terms [that] merely set forth the intended

[6] In this case "an antivenom."

use for ... an otherwise old composition ... do not differentiate the claimed composition from those known in the prior art.").

Appellants make two arguments (one on the record, and the other during Oral Hearing) that require further discussion. The first is that while appellants agree that a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable under 35 U.S.C. § 102, appellants argue that this fundamental principle of patent law does not apply under 35 U.S.C. § 103. Brief, page 6.

Initially, we note that appellants' assertion is in direct contrast to the court's statement in Zierden, "the mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." Appellants, however, are correct in recognizing (Brief, page 6) that Zierden conceded "that his composition, as defined in composition claim 6, is to be patentably distinguished, if at all, from the compositions disclosed in the French patent only by the statement of intended use in the claim." Zierden at 1328, 162 USPQ at 104. However, despite appellants' assertion to the contrary, in our opinion Zierden is not limited solely to rejections under 35 U.S.C. § 102. Brief, page 6. As set forth in Zierden at 1327, 162 USPQ at 103,

> The rejection of the three appealed claims is on the ground of unpatentability over the French patent alone or in view of each of the secondary references, no statutory ground having been stated. The solicitor's brief says it may be considered to be based on both 35 U.S.C. [§] 103 and [§] 102(b). We will so treat it.

Clearly, while there was some confusion in the manner in which the case was prosecuted as to which statutory provision was at issue, in our opinion the

Zierden court treated the case as set forth in the solicitor's brief, specifically, as based on both 35 U.S.C. § 103 and § 102(b); therefore explaining the Zierden court's use of the terms "old" and "obvious", in their statement that "the mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." Zierden, F.2d at 1329, 162 USPQ at 104.

Further, appellants' apparently fail to appreciate that in making the foregoing statement, the Zierden court relied on their holding in In re Lemin, 326 F.2d 437, 440, 140 USPQ 273, 276 (CCPA 1964), "[a]ppellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. [§] 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition." According to the Lemin court, the statement of intended use as it appeared in Lemin's claim failed to provide an "unobvious distinction" over the prior art composition. Id. Accordingly, we disagree with appellants' assertion that a new use for an otherwise obvious composition is sufficient to render an obvious composition patentable.

Second, during Oral Hearing, appellants' representative, Mr. Michael Siekman asserted that under the principles of obviousness a bottle containing a composition (e.g., water) would magically transform into an unobvious composition (e.g., water) simply by changing the directions for using the composition (e.g., the intended use of the water) on the bottle's label. As we

understand it, this issue was resolved more than forty years ago. For clarity, see Lemin,

> Counsel for appellants produced a bottle containing a composition at oral argument. It seems to us that the composition in the bottle would be exactly the same whether the user were told to cure pneumonia in animals with it ... or to promote plant growth with it.... The directions on the label will not change the composition of the contents. We therefore fail to find any unobvious distinction in the claim phrase [reciting the intended use of the claimed composition]....

Accordingly, we are not persuaded by the assertions made by Mr. Siekman during oral argument.

Lastly, we recognize appellants' reliance on In re Mills, 916 F.2d 680, 681-83, 16 USPQ2d 1430, 1432-33 (Fed. Cir. 1990), in support of their argument that Zierden, and Pearson do not apply to the facts on this record. According to appellants, Mills stands for the proposition that "[t]he mere fact that a reference could have been used to achieve the recited functional characteristic does not render a claim obvious in the absence of such a suggestion."

For clarity, we note that the phrase at issue, the intended use phrase, appears in the preamble of appellants' claim 40. Stated differently, the phrase "antivenom pharmaceutical composition for treating a snakebite victim," as it appears in the preamble of claim 40 simply states the intended use for the invention. A preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997); Pitney Bowes, Inc. v. Hewlett-Packard

Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). On this record, the body of claim 40 defines a structurally complete invention.

While appellants rely on Mills, it is unclear how the facts in Mills relate to the issues before us on this record. As we understand it, Mills' invention was to an apparatus, which inter alia, draws air into a mixing chamber by driving an output pump at a capacity greater than the rate at which the ingredients are feed into the machine. See e.g., last clause of Mills' claim 6. According to the court in Mills, 916 F.2d at 682, 16 USPQ2d 1432, Mills' apparatus is different from the prior art because while the feed means of the prior art apparatus can be run at a variable speed it does not require the pump to be run at a lesser speed such that air will be drawn into the mixing chamber, as is required by Mill's claimed apparatus. Finding that the prior art failed to suggest Mill's claimed apparatus, the court reversed the obviousness rejection of record. In our opinion, this is not consistent with the facts on this record.

Stepping away from the facts leading to the courts' holding in Mills' we find some dicta that appears to be consistent with appellants' argument, and is the only portion of Mills that makes reference to 35 U.S.C. § 102. For clarity, we reproduce the first paragraph under the Heading "DISCUSSION" in Mills:

> All of the rejected claims are apparatus claims. The Board found "correspondence in the Mathis reference for all of the subject matter recited in appellants' claims" and that "[t]he Mathis machine discloses all of the structure set forth in claim 1" (a method claim not before us). It asserts that the use of such a mechanism would have been obvious and that the differences between claim 6 and the Mathis machine lie solely in the functional language of the claim, the preamble merely stating an intended use for the machine. This language suggests a lack of novelty rejection under 35 U.S.C. § 102, rather than an obviousness rejection. However,

> no Section 102 rejection has been made or is before us. What is before us is a rejection for obviousness, and we must decide whether the Board erred in that rejection.

We must admit that beyond stating that an anticipation rejection is not before the court on appeal, it is difficult to glean much more insight from this dicta. However, unlike appellants (see Brief, page 6), we do not read Mills as having any distinguishing effect on Zierden and Pearson. Further, as discussed in more detail below, all the elements of appellants' claimed composition are accounted for in the prior art relied upon on this record. Accordingly, we are not persuaded by appellants' reliance on the dicta in Mills.[7]

SUMMARY

For the foregoing reasons, we are not persuaded that the extra words[8] added to the preamble of appellants' claim 40, support the patentability of the claimed composition. As discussed above, and in more detail below, the claimed composition is obvious in view of the prior art of record. "A mere statement of a new use for an otherwise ... obvious composition cannot render a claim to the composition patentable." Zierden, F.2d at 1329, 162 USPQ at 104.

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[7] The remainder of appellants arguments on this record, in addition to the Declarations of record, relate to the use of the claimed composition as an antivenom. Since we have placed not weight on the intended use of appellants' composition we do not address these arguments or the Declarations.

[8] Specifically, the phrase "pharmaceutical composition for treating a snakebite victim."

II. Neutralizes the lethality of the venom of a snake of the Crotalus genus:

The second difference between claim 40 as it appeared in the '1255 appeal and claim 40 as it appears before us on this record is the insertion of a functional limitation that requires the composition to have the property of neutralizing the lethality of the venom of a snake of the Crotalus genus.

Sullivan, however, teaches (page 186, 187 and tables 2 and 3), neutralization of the lethality of the venom of a snake of the Crotalus genus. In addition, Coulter teach (page 202), "[t]he neutralization tests performed in mice showed that on a weight basis the IgG and Fab anti-textilotoxin preparations were equivalent in neutralizing ability," demonstrating that Fab fragments of neutralizing antibodies retain their ability to neutralize toxins.

Accordingly, the composition taught by the combination of Sullivan and Coulter that comprises

1. Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and

2. a pharmaceutically acceptable carrier,

would also be expected, by a person of ordinary skill in the art at the time the invention was made to neutralize the lethality of the venom of a snake of the Crotalus genus as required by appellants' claim 40.

SUMMARY

For the foregoing reasons, we are not persuaded that the additional requirement that the composition of claim 40 neutralize the lethality of the venom of a snake of the Crotalus genus, supports the patentability of the claimed

composition. This property of the Fab fragments to neutralize the lethality of the snakes venom would not make the Fab fragments any less useful for EIAs to detect said venom. Accordingly, as we stated at page 9 of the Decision of the '1255 appeal

> we agree with the examiner's conclusion a person of ordinary skill in the art would have produced F(ab) fragments against Crotalus venom (as taught by Sullivan) for use in EIAs to detect said venom, since Coulter teach that F(ab) fragments provide the EIA with a higher degree of sensitivity. In this regard, we note that Coulter was motivated to prepare Fab fragments due to their "investigation of the binding site(s) of snake neurotoxin at the neuromuscular junction."

Appellants did not dispute this finding in the '1255 appeal, nor do they dispute this finding on this appeal. Accordingly, we find that appellants' have conceded to this issue.

III. Conclusion:

As discussed above, the combination of Sullivan and Coulter teach a composition comprising Fab fragments which

1. specifically bind to the venom of a snake of the Crotalus genus,
2. are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies,
3. are in a pharmaceutically acceptable carrier, and
4. neutralize the lethality of the venom of a snake of the Crotalus genus.

As discussed above, a person of ordinary skill in the art would have produced Fab fragments against Crotalus venom (as taught by Sullivan) for use in EIAs to detect said venom, since Coulter teach that Fab fragments provide the

EIA with a higher degree of sensitivity. These Fab fragments also have the ability to neutralize the lethality of the venom of a snake of the Crotalus genus, this property of the Fab fragments, however, does not affect their use in EIAs. In this regard, we note that Coulter was motivated to prepare Fab fragments due to their "investigation of the binding site(s) of snake neurotoxin at the neuromuscular junction."

While, as the preamble of claim 40 suggests, appellants intend to use the claimed Fab fragments as an antivenom pharmaceutical composition for treating a snakebite victim, "the mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." Zierden.

Accordingly, we affirm the rejection of claim 40 under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter. As discussed above claims 41, 42 and 50 fall together with claim 40.

Sullivan in view of Coulter, Smith and Stedman's:

Claims 40-42 and 50 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter, Smith and Stedman's.
We affirm rejection I. Having disposed of all claims on appeal obvious over the combination of Sullivan and Coulter we do not reach the merits of the rejection of claims 40-42 and 50 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter, Smith and Stedman's.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams)
Administrative Patent Judge)
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)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
Administrative Patent Judge)

DA/dym

Michael T. Siekman
WOLF, GREENFIELD & SACKS, P. C.
600 Atlantic Avenue
Boston MA 02210